Tab 9

DEC 1 4 2001

K013327

Premarket Notification [510(k)] Summary

August 24,2001

Trade Name: CTS-415 with C3I40 and L7I50 Transducers

Common Name: Diagnostic Ultrasound System

Classification Name: Ultrasonic Pulsed Echo Imaging System, 90 IYO
(per 21 CFR section 892.1560)

Manufacturer's Name: Shantou Institute of Ultrasonic Instruments

Address: #77, Jinsha Road,
Shantou Sez, 515041, China

Corresponding Official: Mr. Jinzhong Yao

Title: President

Telephone: (86) 754-8250150 Fax: (86) 754-8251499

Predicate: Hitachi Medical Corporation EUB-310, K862867

Device Description: Model CTS-415 is a linear/convex electronic scanning ultrasonotomograph with a built-in digital scan converter (DSC) and main CPU module. The unit allows heart, abdominal organic and fetal tomographic images to be observable on a video monitor. The main unit is portable and is separable from other equipment to be carried for its use at another place as well as being usable in combination with a 9-inch video monitor and a special photographic unit.

Intended Use: Ultrasonic pulsed echo imaging and measurement for fetal imaging and other abdominal as well as pediatric, small organ cardiac.

Technological Characteristics:

(1) Scanning method: Electronic convex sector scanning, linear scanning
(2) Display mode: B, B/B, B/M, M
(3) Grey scale: 256
(4) Frequency of probe: 2.5MHz to 9.0MHz
(5) Image Display multiple: X1.0, X1.5, X2.0; Shift 2mm step
(6) Focusing method: Variable aperture 1-4 focal zone electronic focusing
(7) Display range (max):
Depth 220mm angle 82° (Convex)

Depth 120mm width 50mm (Linear 5.0MHz)

(8) Image adjustment

Gain: 0 to 99 (digital)
Near Gain: 0 to –60 (digital)
Far Gain: 0 to 6.0 (digital)
Grey map curve: 8 types
Frame Correlation: 4 steps
Edge Enhance: 4 steps

(9) Sweep Speed in M Mode: 1, 2, 4, 8sec/frame

(10) Image Display: left/right, positive/negative

(11) Cineloop: up to 64 frames, continual/single

(12) DSC memory capacity: 512 X 512 X 8 bit

(13) Monitor: 9-inch B/W monitor

(14) Character display

(a) Patient's ID
(b) Hospital Name
(c) Comment
(d) Automatically Display Items: Date & time, probe frequency, gain and other operating parameters, and various measured values.

(15) Body marks: 25 types

(16) Measuring functions:

(a) Basic measurement: distance, circumference, area, volume, angle, HR
(b) Obstetrics measurement: BPD, CRL, FL, AC, HC, GS, VOL, ANG
(c) Other measurements:

(17) I/O port

(a) RS-232C port for transmitting image to PC
(b) One active convex or linear array ports

(18) Video system: 625lines/frame, 50fields/second (PAL)
or 525lines/frame, 60fields/second (NTSC)

(19) Dimension 395(W) x 728(L) x 1180(H) mm

(20) Net Weight: about 50kg

(21) Power Consumption: ~220V±10%, 100VA
Or ~110V±10%, 100VA

(22) Environmental Requirements:

(a) Operating Temperature & Humidity: 0°C to 40°C, 30% to 85%RH
(b) Atmospheric Pressure: 70 to 106 KPa (700 to 1060 mbars)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

Shantou Institute of Ultrasonic Instruments
% Mr. Bob Leiker
Quality and Regulatory Services
1106 Chiltern Drive
WALNUT CREEK CA 94596

Re: K013327
Trade Name: CTS-415 Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: 90 IYO
Reagulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Product Code: 90 ITX
Regulatory Class: II
Dated: August 24, 2001
Received: October 5, 2001

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CTS-415 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

3.5 MHz C3I40 Curved Array Probe
7.5 MHz L7I50 Linear Array Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

3.3 SIUI CTS-415 Ultrasound Imaging System

K013327

Indications for Use Form

Diagnostic Ultrasound System Indications for Use Form

Device Name: CTS-415

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethrat										
Intravascular										
Perpheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal superficial										
Other (specify)										

N=new indication

Additional Comments: Small organs includes: thyroid, parathyroid, parotid, submaxillary gland, testes and breast

Pediatric Comments: Pediatric Intended Uses include: Cardiology, Abdomen, Peripheral Vasa

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013327

009

3.1 SIUI CTS-415 Ultrasound Imaging System

Scanhead Indications for Use Form
Device Name: Convex Array C3I40

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethrat										
Intravascular										
Perpheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal superficial										
Other (specify)										

N=new indication

Additional Comments: Pediatric Comments: Pediatric Intended Uses include: Cardiology, Abdomen

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013327

3.2 SIUI CTS-415 Ultrasound Imaging System

Scanhead Indications for Use Form

Device Name: Linear Array L7I50

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethrat										
Intravascular										
Perpheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal superficial										
Other (specify)										

N=new indication

Additional Comments: Small organs includes: thyroid, parathyroid, parotid, submaxillary gland, testes and breast

Pediatric Comments: Pediatric Intended Uses include: Peripheral Vasa

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013327